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| 10/052,771      | 01/23/2002  | John A. Schillinger  | N1206-373           | 7104             |

7590 09/26/2005

Robert E Hanson  
FULBRIGHT & JAWORSKI LLP  
Suite 2400  
600 Congress Avenue  
Austin, TX 78701

EXAMINER

PARA, ANNETTE H

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1661

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/052,771

Applicant(s)

SCHILLINGER ET AL.

Examiner

Annette H. Para

Art Unit

1661

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on July 1, 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-10,13,25,33,35,39,42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 25,33,35,39,42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 1, 2005 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The specification is objected to for including a drawing (Scheme 1, page 13) within the text of the specification. This portion of the specification should be cancelled and resubmitted as a drawing; an appropriate description of the figure should also be amended into the specification.

The rejection of claims 1,2,4-10, and 13 under 35 USC 103 as being unpatentable over Padgett et al. in view of Songstad et al. and further in view of Krueger is withdrawn in favor of the art rejection below.

### ***Claim Rejections - 35 USC § 112***

Claims 1, 2, 4-10, and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is modified from the rejection set forth in the office action mailed on September 23, 2004 as applied to claims 1,2,4-10, and 13. Applicants' arguments and the Declaration of Donald Steffen, both filed on July 1, 2005 have been fully considered but they are not persuasive.

The claims are broadly drawn to soybean seeds or plants comprising genes conferring resistance to glyphosate and glufosinate wherein the genes may be transgenes or mutant versions of soybean genes.

Soybean plants comprising a transgene conferring resistance to glyphosate or glufosinate are well known in the art and are described in the specification. No soybean plants comprising mutant soybean genes conferring resistance to glyphosate and glufosinate are described in the specification or in the art. The specification does not describe the structure of any soybean gene required for the function of conferring resistance to glyphosate or glufosinate.

Hence, Applicants have not described soybean plants or seeds comprising genes conferring resistance to glyphosate or glufosinate within the full scope of the claims, and the specification fails to provide an adequate written description for the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the full scope of the claimed soybean plants or seeds. Applicants were not in possession of the full scope of the claimed genes at the time this application was filed.

Applicants urge that deposit of seeds for cultivars 924181339, which exhibits resistance to glyphosate herbicide and of seeds for cultivar 89248009206, which exhibits resistance to glufosinate herbicides, was made. They also state that the seed deposits fully describe genes encoding resistance to glufosinate and glyphosate. This is not found persuasive because none of the deposited lines describe mutant soybean genes conferring resistance to glyphosate or glufosinate.

Applicants urge that the possession of the invention is demonstrated by working examples (response p. 5). The Declaration of Donald Steffen presents evidence that the application discloses a soybean plant comprising genes conferring resistance to glyphosate, glufosinate and ALS inhibitor herbicides (Declaration on ¶¶ 5-6).

This is not found persuasive because the genes conferring resistance to glyphosate and glufosinate in the plant are not mutant soybean genes but are instead transgenes. Thus, the specification

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does not describe soybean plants comprising mutant soybean genes conferring resistance to glyphosate and glufosinate.

Claims 1, 3, 4-10, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for soybean seeds and plants comprising genes conferring resistance to glyphosate and glufosinate wherein the resistance is conferred by transgenes, does not reasonably provide enablement for soybean seeds and plants comprising genes conferring resistance to glyphosate and glufosinate, wherein the resistance is conferred by mutations in soybean genes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The rejection is modified from the rejection set forth in the office action mailed on September 23, 2004 as applied to claims 1,2,4-10, and 13. Applicant's argument and the Declaration of Donald Steffen both filed on July 1, 2005 have been fully considered but they are not persuasive.

The claims are broadly drawn to a transgenic or nontransgenic soybean seed, plant, pollen, ovule, and tissue culture comprising genes conferring resistance to at least the herbicides glyphosate and glufosinate.

The specification, however only provides prophetic guidance for transforming a plant by micro projectile bombardment with genes conferring resistance to glyphosate and glufosinate, wherein the genes are on the same or separate construct (example 1). The specification also describes deposited soybean line 924181339, which has resistance to glyphosate and sulfonylurea (example 2), deposited soybean line 928933959, which has resistance to glyphosate and sulfonylurea (example 3), deposited soybean line 92417111, which has resistance to glyphosate and sulfonylurea (example 4), deposited soybean line 93233925295, which has resistance to glyphosate and sulfonylurea (example 5), deposited soybean line 89248009206, which has resistance to sulfonylurea and glufosinate (example 6). The specification provides guidance for methods of testing resistance to multiple herbicides (examples 7-12).

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The specification also discusses undeposited soybean line A2704, which has resistance to glyphosate, glufosinate, and sulfonylurea.

Mutant soybean genes conferring resistance to glufosinate and glyphosate are not taught in the specification or known in the art. Resistance to glufosinate and glyphosate is only conferred by transgene (Mallory-Smith et al. Possible pleiotropic effects in herbicide-resistant crops paragraph 3 page 205 and page 207 paragraph 2), and Muellner et al. (Engineering Crop Resistance to the Naturally Occurring Glutamine Synthetase Inhibitor Phosphinothricin pages 38-47) teach that it was not possible to select mutant plants with usable levels of glufosinate resistance (§3 page 43, ¶1 page 44) Furthermore, Rose-Fricker (2000, US Patent 6,066,786 column 1, lines 41-42) teaches glyphosate resistance is very rare in nature (column 1, lines 41-42). The specification does not teach how to make soybean plants comprising mutant soybean genes conferring resistance to glyphosate and glufosinate.

As the specification does not describe any soybean plant comprising mutant soybean genes conferring resistance to glyphosate and glufosinate, undue trial and error experimentation would be required to screen through the myriad of existing soybean lines to identify those with resistance to glyphosate and glufosinate, if such plants are even obtainable.

Given the claim breadth, unpredictability in the art, undue experimentation and lack of guidance in the specification as discussed above, the instant specification is not enable throughout the full scope of the claims.

Applicants urge that the enablement of the claims is fully established by the working examples, and the Declaration of Donald Steffen summarizes this (response pg. 7-8, Declaration ¶ 5-6). This is not found persuasive because the working examples describe genes conferring resistance to glyphosate and glufosinate in the plant, which are not mutant soybean genes but are instead transgenes.

Applicants urge that the claims do not require stacking more than two resistance genes (response pg. 8). This is not persuasive because the claims are not enabled for stacking those two resistance genes, wherein the resistance genes are mutant soybean genes

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Applicants urge that all the required material and method steps are provided by the specification and genes conferring resistance are known in the art (response pg. 8-9) This is not found persuasive because mutant soybean genes conferring resistance were not known in the art as summarized by Rose-Fricker and Muellner et al. and not taught in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite in its recitation of "commercially acceptable grain yield". This phrase is a relative phrase not defined by the specification. It is not clear what level of grain yield is commercially acceptable.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C.103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 2, 4-10, and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Padgett et al. (Crop Science 35:1451-1461. 1995) in view of Russell et al. (EPO 0430511A1) and further in view of Hacker et al. (U.S. Patent No. 5,599,769 1997).

The claims are drawn to soybean plants and seeds comprising genes conferring resistance to glyphosate and glufosinate herbicides.

Padgett et al. teach soybean seeds and plants that have resistance to glyphosate via transformation with a gene from *Agrobacterium*. (page 1452) Padgett et al. also teach use of said resistant plant in crosses to produce hybrid soybean plants that are resistant to glyphosate (see page 1455). Padgett et al. do not teach soybean plants that are resistant to glufosinate.

Russell et al. teach soybean plants that have resistance to glutamine synthetase inhibitor via transformation. At the time of the invention was filed it would have been obvious to one of the ordinary skill in the art to modify the soybean plant as taught by Padgett et al. by crossing it with the soybean plant as described in Russell et al. Hacker et al. teach herbicidal compounds containing more than one herbicide, including both glufosinate and glyphosate (column 1, lines 37-39) and that they have a broad spectrum of herbicidal activity (column 3, lines 54-57). As the herbicide-resistance genes are used in crop plants so they will be resistant when herbicides are applied (see Russell page 2, lines 47-49; Padgett page 1451, column 1, paragraph 1), one ordinary skill in the art would have been motivated to develop soybean plants comprising genes conferring resistance to at least glyphosate and glufosinate to take full advantage of the synergetic effects of using multiple herbicides on crop fields.

. Thus the claimed invention would have been prima facie obvious as a whole at the time it was made, especially in the absence of evidence to the contrary.

#### **Future Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette H Para whose telephone number is (571) 272-0982. The examiner can normally be reached Monday through Thursday from 5:30 a.m. to 4:00 p.m.



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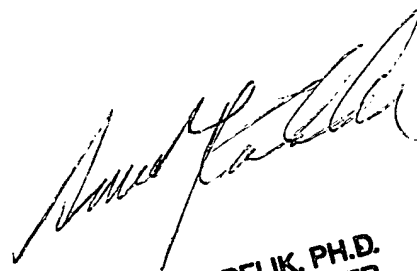
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax number for the organization where the application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about PAIR system, see <http://pair-direct.uspto.gov> . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Annette H Para

September 19, 2005



ANNE KUBELIK, PH.D.  
PRIMARY EXAMINER